

5

What is claimed is:

1. A lead electrode assembly for subcutaneous implantation comprising:

an electrode;

10 a riser coupled to the electrode; and  
a head coupled to the riser.

2. The lead electrode assembly of claim 1, wherein the riser comprises a metallic material.

3. The lead electrode assembly of claim 2, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

20 4. The lead electrode assembly of claim 1, wherein the riser comprises a polymeric material.

5. The lead electrode assembly of claim 4, wherein the 25 polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a

5 polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

6. The lead electrode assembly of claim 1, wherein the head comprises a metallic material.

10

7. The lead electrode assembly of claim 6, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

SEARCHED INDEXED  
SERIALIZED FILED

8. The lead electrode assembly of claim 1, wherein the head comprises a polymeric material.

9. The lead electrode assembly of claim 8, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

25

10. The lead electrode assembly of claim 1, wherein the riser is substantially planar.

5        11. The lead electrode assembly of claim 1, wherein the riser is substantially perpendicular to the electrode.

12. The lead electrode assembly of claim 1, wherein the riser is substantially centered over the electrode.

10

13. The lead electrode assembly of claim 1, wherein the head is substantially planar.

14. The lead electrode assembly of claim 1, wherein the head is substantially perpendicular to the riser.

15. The lead electrode assembly of claim 1, wherein the riser is between approximately 1 mm and approximately 10 mm in height.

PCT/US2003/03520

16. The lead electrode assembly of claim 15, wherein the riser comprises a proximal end, a distal end, a top and a bottom and wherein the proximal end is closer to the distal end at the top of the riser than at the bottom of the riser.

25

17. The lead electrode assembly of claim 1, wherein the electrode comprises a mesh of metallic material.

5        18. The lead electrode assembly of claim 17, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

10      19. The lead electrode assembly of claim 1, wherein the electrode comprises a substantially flat sheet of metallic material.

15      20. The lead electrode assembly of claim 19, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

20      21. The lead electrode assembly of claim 1, wherein the electrode is substantially planar.

25      22. The lead electrode assembly of claim 1, wherein the electrode comprises at least one substantially planar surface.

25      23. The lead electrode assembly of claim 22, wherein the at least one substantially planar surface has a surface area between approximately 100 square millimeters and approximately 2000 square millimeters.

5

24. The lead electrode assembly of claim 1, wherein the lead electrode assembly further comprises a lead coupled to the electrode.

10 25. The lead electrode assembly of claim 24, wherein the lead comprises one or more electrical conductors electrically coupled to the electrode.

05 26. The lead electrode assembly of claim 25, wherein the lead further comprises an electrically insulating sheath, enclosing the one or more electrical conductors.

10 27. The lead electrode assembly of claim 24, wherein the lead electrode assembly further comprises a connector coupled to the lead.

20 28. The lead electrode assembly of claim 27, wherein the connector is electrically coupled to the electrode.

25 29. The lead electrode assembly of claim 24, wherein the lead is between approximately 5 cm and approximately 52 cm in length.

5       30. The lead electrode assembly of claim 29, wherein the lead is between approximately 5 cm and approximately 30 cm in length.

10      31. The lead electrode assembly of claim 30, wherein the lead is between approximately 10 cm and approximately 20 cm in length.

15      32. The lead electrode assembly of claim 29, wherein the lead length is one of a plurality of pre-set lengths.

20      33. The lead electrode assembly of claim 32, wherein the pre-set lengths vary by approximately 10 cm.

25      34. The lead electrode assembly of claim 24, wherein the lead has a proximal end and a distal end and wherein the proximal end of the lead is coupled to the electrode.

30      35. The lead electrode assembly of claim 34, wherein the lead electrode assembly further comprises a lead fastener coupled between the proximal end of the lead and the electrode.

5       36. The lead electrode assembly of claim 35, wherein the riser is coupled to the electrode along an interface line intersecting the lead fastener.

10      37. The lead electrode assembly of claim 35, wherein the riser is coupled to the electrode along an interface line and wherein the lead is coupled to the lead fastener along a line of the lead that is substantially parallel to the interface line.

15      38. The lead electrode assembly of claim 37, wherein the interface line and the line of the lead are the same line.

20      39. The lead electrode assembly of claim 1, wherein the length of the riser is between approximately 2 mm and approximately 6 cm.

25      40. The lead electrode assembly of claim 1, wherein the length of the riser is less than the length of the electrode.

30      41. The lead electrode assembly of claim 40, wherein the riser is coupled to the electrode along an interface line and the length of the riser and the length of the electrode are measured along the interface line.

5        42. The lead electrode assembly of claim 41, wherein the electrode has a proximal end and a distal end and wherein the riser is closer to the proximal end of the electrode than the distal end of the electrode.

10      43. The lead electrode assembly of claim 42, wherein the lead electrode assembly further comprises a lead, wherein the lead is coupled to the electrode closer to the distal end of the electrode than the proximal end of the electrode.

SEARCHED  
INDEXED  
SERIALIZED  
FILED

15      44. The lead electrode assembly of claim 43, wherein the lead electrode assembly further comprises a lead fastener coupled between the lead and the electrode.

20      45. The lead electrode assembly of claim 1, wherein the lead electrode assembly further comprises a foundation.

46. The lead electrode assembly of claim 45, wherein a top surface of the foundation is coupled to a bottom of the riser.

25      47. The lead electrode assembly of claim 45, wherein a bottom surface of the foundation is coupled to and faces a top surface of the electrode.

5       48. The lead electrode assembly of claim 45, wherein the lead electrode assembly further comprises a backing layer coupled between the foundation and the electrode.

10      49. The lead electrode assembly of claim 46, wherein the backing layer comprises a polymeric material.

15      50. The lead electrode assembly of claim 49, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

20      51. The lead electrode assembly of claim 45, wherein the lead electrode assembly further comprises a molded cover coupled to the foundation and the electrode.

25      52. The lead electrode assembly of claim 51, wherein the molded cover at least partially covers a top surface of the foundation.

5        53. The lead electrode assembly of claim 51, wherein the  
molded cover comprises a skirt that partially covers a bottom  
surface of the electrode.

10      54. The lead electrode assembly of claim 51, wherein the  
molded cover comprises a polymeric material.

15      55. The lead electrode assembly of claim 54, wherein the  
polymeric material is selected from the group consisting  
essentially of a polyurethane, a polyamide, a  
polyetheretherketone (PEEK), a polyether block amide (PEBA), a  
polytetrafluoroethylene (PTFE), a silicone, and mixtures  
thereof.

20      56. The lead electrode assembly of claim 45, wherein the  
foundation is substantially planar.

57. The lead electrode assembly of claim 45, wherein the  
foundation is substantially parallel to the electrode.

25      58. The lead electrode assembly of claim 45, wherein the  
foundation comprises a metallic material.

5        59. The lead electrode assembly of claim 58, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

10      60. The lead electrode assembly of claim 45, wherein the foundation comprises a polymeric material.

15      61. The lead electrode assembly of claim 60, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

20      62. A lead electrode assembly for use with an implantable cardioverter-defibrillator subcutaneously implanted outside the ribcage between the third and twelfth ribs comprising:

25                  an electrode;  
                a riser coupled to the electrode; and  
                a head coupled to the riser.

63. The lead electrode assembly of claim 62, wherein the riser comprises a metallic material.

5

64. The lead electrode assembly of claim 63, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

10

65. The lead electrode assembly of claim 62, wherein the riser comprises a polymeric material.

0  
5  
10  
15  
20

66. The lead electrode assembly of claim 65, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

67. The lead electrode assembly of claim 62, wherein the head comprises a metallic material.

68. The lead electrode assembly of claim 67, wherein the 25 metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

5        69. The lead electrode assembly of claim 62, wherein the head comprises a polymeric material.

10      70. The lead electrode assembly of claim 69, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

SEARCHED INDEXED  
SERIALIZED FILED  
JULY 22 1998

15      71. The lead electrode assembly of claim 62, wherein the riser is substantially planar.

20      72. The lead electrode assembly of claim 62, wherein the riser is substantially perpendicular to the electrode.

25      73. The lead electrode assembly of claim 62, wherein the riser is substantially centered over the electrode.

74. The lead electrode assembly of claim 62, wherein the  
25 head is substantially planar.

75. The lead electrode assembly of claim 62, wherein the head is substantially perpendicular to the riser.

5

76. The lead electrode assembly of claim 62, wherein the riser is between approximately 1 mm and approximately 10 mm in height.

10 77. The lead electrode assembly of claim 76, wherein the riser comprises a proximal end, a distal end, a top and a bottom and wherein the proximal end is closer to the distal end at the top of the riser than at the bottom of the riser.

DE202007002381.0

78. The lead electrode assembly of claim 62, wherein the electrode comprises a mesh of metallic material.

15 79. The lead electrode assembly of claim 78, wherein the metallic material is selected from the group consisting of essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

20 80. The lead electrode assembly of claim 62, wherein the electrode comprises a substantially flat sheet of metallic material.

25 81. The lead electrode assembly of claim 80, wherein the metallic material is selected from the group consisting

5 essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

82. The lead electrode assembly of claim 62, wherein the electrode is substantially planar.

10

83. The lead electrode assembly of claim 62, wherein the electrode comprises at least one substantially planar surface.

0  
5  
10  
15  
20  
25

84. The lead electrode assembly of claim 83, wherein the at least one substantially planar surface has a surface area between approximately 100 square millimeters and approximately 2000 square millimeters.

85. The lead electrode assembly of claim 62, wherein the lead electrode assembly further comprises a lead coupled to the electrode.

25  
86. The lead electrode assembly of claim 85, wherein the lead comprises one or more electrical conductors electrically coupled to the electrode.

5        87. The lead electrode assembly of claim 86, wherein the lead further comprises an electrically insulating sheath, enclosing the one or more electrical conductors.

10      88. The lead electrode assembly of claim 85, wherein the lead electrode assembly further comprises a connector coupled to the lead.

15      89. The lead electrode assembly of claim 88, wherein the connector is electrically coupled to the electrode.

20      90. The lead electrode assembly of claim 85, wherein the lead is between approximately 5 cm and approximately 52 cm in length.

25      91. The lead electrode assembly of claim 90, wherein the lead is between approximately 5 cm and approximately 30 cm in length.

30      92. The lead electrode assembly of claim 91, wherein the lead is between approximately 10 cm and approximately 20 cm in length.

5        93. The lead electrode assembly of claim 90, wherein the  
lead length is one of a plurality of pre-set lengths.

94. The lead electrode assembly of claim 93, wherein the pre-set lengths vary by approximately 10 cm.

10

95. The lead electrode assembly of claim 85, wherein the lead has a proximal end and a distal end and wherein the proximal end of the lead is coupled to the electrode.

Digitized by Google

96. The lead electrode assembly of claim 95, wherein the lead electrode assembly further comprises a lead fastener coupled between the proximal end of the lead and the electrode.

97. The lead electrode assembly of claim 96, wherein the riser is coupled to the electrode along an interface line intersecting the lead fastener.

98. The lead electrode assembly of claim 96, wherein the  
riser is coupled to the electrode along an interface line and  
wherein the lead is coupled to the lead fastener along a line of  
the lead that is substantially parallel to the interface line.

5        99. The lead electrode assembly of claim 98, wherein the interface line and the line of the lead are the same line.

100. The lead electrode assembly of claim 62, wherein the length of the riser is between approximately 2 mm and  
10 approximately 6 cm.

101. The lead electrode assembly of claim 62, wherein the length of the riser is less than the length of the electrode.

102. The lead electrode assembly of claim 101, wherein the riser is coupled to the electrode along an interface line and the length of the riser and the length of the electrode are measured along the interface line.

103. The lead electrode assembly of claim 102, wherein the electrode has a proximal end and a distal end and wherein the riser is closer to the proximal end of the electrode than the distal end of the electrode.

25        104. The lead electrode assembly of claim 103, wherein the lead electrode assembly further comprises a lead, wherein the lead is coupled to the electrode closer to the distal end of the electrode than the proximal end of the electrode.

5

105. The lead electrode assembly of claim 104, wherein the lead electrode assembly further comprises a lead fastener coupled between the lead and the electrode.

10 106. The lead electrode assembly of claim 62, wherein the lead electrode assembly further comprises a foundation.

107. The lead electrode assembly of claim 106, wherein a top surface of the foundation is coupled to a bottom of the riser.

108. The lead electrode assembly of claim 106, wherein a bottom surface of the foundation is coupled to and faces a top surface of the electrode.

109. The lead electrode assembly of claim 106, wherein the lead electrode assembly further comprises a backing layer coupled between the foundation and the electrode.

25 110. The lead electrode assembly of claim 107, wherein the backing layer comprises a polymeric material.

5        111. The lead electrode assembly of claim 110, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures  
10 thereof.

112. The lead electrode assembly of claim 106, wherein the lead electrode assembly further comprises a molded cover coupled to the foundation and the electrode.

113. The lead electrode assembly of claim 112, wherein the molded cover at least partially covers a top surface of the foundation.

114. The lead electrode assembly of claim 112, wherein the molded cover comprises a skirt that partially covers a bottom surface of the electrode.

115. The lead electrode assembly of claim 112, wherein the 25 molded cover comprises a polymeric material.

116. The lead electrode assembly of claim 115, wherein the polymeric material is selected from the group consisting

5 essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

10 117. The lead electrode assembly of claim 106, wherein the foundation is substantially planar.

118. The lead electrode assembly of claim 106, wherein the foundation is substantially parallel to the electrode.

119. The lead electrode assembly of claim 106, wherein the foundation comprises a metallic material.

120. The lead electrode assembly of claim 119, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

121. The lead electrode assembly of claim 106, wherein the 25 foundation comprises a polymeric material.

122. The lead electrode assembly of claim 121, wherein the polymeric material is selected from the group consisting

5 essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

10 123. A lead electrode assembly for subcutaneous implantation in a patient's posterior thorax from an incision in the skin covering the patient's anterior thorax comprising:  
an electrode;  
a riser coupled to the electrode; and  
a head coupled to the riser.

15 124. The lead electrode assembly of claim 123, wherein the riser comprises a metallic material.

20 125. The lead electrode assembly of claim 124, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

25 126. The lead electrode assembly of claim 123, wherein the riser comprises a polymeric material.

5        127. The lead electrode assembly of claim 126, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

10      128. The lead electrode assembly of claim 123, wherein the head comprises a metallic material.

15      129. The lead electrode assembly of claim 128, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

20      130. The lead electrode assembly of claim 123, wherein the head comprises a polymeric material.

25      131. The lead electrode assembly of claim 130, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

5

132. The lead electrode assembly of claim 123, wherein the riser is substantially planar.

133. The lead electrode assembly of claim 123, wherein the  
10 riser is substantially perpendicular to the electrode.

134. The lead electrode assembly of claim 123, wherein the riser is substantially centered over the electrode.

135. The lead electrode assembly of claim 123, wherein the head is substantially planar.

136. The lead electrode assembly of claim 123, wherein the head is substantially perpendicular to the riser.

137. The lead electrode assembly of claim 123, wherein the riser is between approximately 1 mm and approximately 10 mm in height.

25        138. The lead electrode assembly of claim 137, wherein the  
riser comprises a proximal end, a distal end, a top and a bottom  
and wherein the proximal end is closer to the distal end at the  
top of the riser than at the bottom of the riser.

5

139. The lead electrode assembly of claim 123, wherein the electrode comprises a mesh of metallic material.

140. The lead electrode assembly of claim 139, wherein the 10 metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

SEARCHED INDEXED  
SERIALIZED FILED  
JUN 20 2003

141. The lead electrode assembly of claim 123, wherein the electrode comprises a substantially flat sheet of metallic material.

142. The lead electrode assembly of claim 141, wherein the 20 metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

143. The lead electrode assembly of claim 123, wherein the electrode is substantially planar.

25

144. The lead electrode assembly of claim 123, wherein the electrode comprises at least one substantially planar surface.

5        145. The lead electrode assembly of claim 144, wherein the at least one substantially planar surface has a surface area between approximately 100 square millimeters and approximately 2000 square millimeters.

10      146. The lead electrode assembly of claim 123, wherein the lead electrode assembly further comprises a lead coupled to the electrode.

147. The lead electrode assembly of claim 146, wherein the lead comprises one or more electrical conductors electrically coupled to the electrode.

148. The lead electrode assembly of claim 147, wherein the lead further comprises an electrically insulating sheath, enclosing the one or more electrical conductors.

149. The lead electrode assembly of claim 146, wherein the lead electrode assembly further comprises a connector coupled to the lead.

25

150. The lead electrode assembly of claim 149, wherein the connector is electrically coupled to the electrode.

5        151. The lead electrode assembly of claim 146, wherein the lead is between approximately 5 cm and approximately 52 cm in length.

10      152. The lead electrode assembly of claim 151, wherein the lead is between approximately 5 cm and approximately 30 cm in length.

15      153. The lead electrode assembly of claim 152, wherein the lead is between approximately 10 cm and approximately 20 cm in length.

20      154. The lead electrode assembly of claim 151, wherein the lead length is one of a plurality of pre-set lengths.

25      155. The lead electrode assembly of claim 154, wherein the pre-set lengths vary by approximately 10 cm.

156. The lead electrode assembly of claim 146, wherein the lead has a proximal end and a distal end and wherein the proximal end of the lead is coupled to the electrode.

5        157. The lead electrode assembly of claim 156, wherein the lead electrode assembly further comprises a lead fastener coupled between the proximal end of the lead and the electrode.

10      158. The lead electrode assembly of claim 157, wherein the riser is coupled to the electrode along an interface line intersecting the lead fastener.

15      159. The lead electrode assembly of claim 157, wherein the riser is coupled to the electrode along an interface line and wherein the lead is coupled to the lead fastener along a line of the lead that is substantially parallel to the interface line.

20      160. The lead electrode assembly of claim 159, wherein the interface line and the line of the lead are the same line.

25      161. The lead electrode assembly of claim 123, wherein the length of the riser is between approximately 2 mm and approximately 6 cm.

162. The lead electrode assembly of claim 123, wherein the length of the riser is less than the length of the electrode.

5        163. The lead electrode assembly of claim 162, wherein the riser is coupled to the electrode along an interface line and the length of the riser and the length of the electrode are measured along the interface line.

10      164. The lead electrode assembly of claim 163, wherein the electrode has a proximal end and a distal end and wherein the riser is closer to the proximal end of the electrode than the distal end of the electrode.

00000000000000000000000000000000

15      165. The lead electrode assembly of claim 164, wherein the lead electrode assembly further comprises a lead, wherein the lead is coupled to the electrode closer to the distal end of the electrode than the proximal end of the electrode.

20      166. The lead electrode assembly of claim 165, wherein the lead electrode assembly further comprises a lead fastener coupled between the lead and the electrode.

25      167. The lead electrode assembly of claim 123, wherein the lead electrode assembly further comprises a foundation.

5        168. The lead electrode assembly of claim 167, wherein a top surface of the foundation is coupled to a bottom of the riser.

10      169. The lead electrode assembly of claim 167 wherein a bottom surface of the foundation is coupled to and faces a top surface of the electrode.

15      170. The lead electrode assembly of claim 167, wherein the lead electrode assembly further comprises a backing layer coupled between the foundation and the electrode.

20      171. The lead electrode assembly of claim 168, wherein the backing layer comprises a polymeric material.

25      172. The lead electrode assembly of claim 171, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

5        173. The lead electrode assembly of claim 167, wherein the lead electrode assembly further comprises a molded cover coupled to the foundation and the electrode.

10      174. The lead electrode assembly of claim 173, wherein the molded cover at least partially covers a top surface of the foundation.

15      175. The lead electrode assembly of claim 173, wherein the molded cover comprises a skirt that partially covers a bottom surface of the electrode.

20      176. The lead electrode assembly of claim 173, wherein the molded cover comprises a polymeric material.

25      177. The lead electrode assembly of claim 176, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

178. The lead electrode assembly of claim 167, wherein the foundation is substantially planar.

5

179. The lead electrode assembly of claim 167, wherein the foundation is substantially parallel to the electrode.

180. The lead electrode assembly of claim 167, wherein the 10 foundation comprises a metallic material.

181. The lead electrode assembly of claim 180, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

182. The lead electrode assembly of claim 167, wherein the foundation comprises a polymeric material.

183. The lead electrode assembly of claim 182, wherein the 20 polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

25

184. An implantable cardioverter-defibrillator for subcutaneous positioning between the third rib and the twelfth

5 rib within a patient, the implantable cardioverter-defibrillator comprising:

a housing; and

a lead electrode assembly coupled to the housing,  
wherein the lead electrode assembly comprises:

10 an electrode;

a riser coupled to the electrode; and  
a head coupled to the riser.

185. The implantable cardioverter-defibrillator of claim 184, wherein the riser comprises a metallic material.

186. The implantable cardioverter-defibrillator of claim 185, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

187. The implantable cardioverter-defibrillator of claim 184, wherein the riser comprises a polymeric material.

25 188. The implantable cardioverter-defibrillator of claim 187, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a

5 polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

189. The implantable cardioverter-defibrillator of claim 184, wherein the head comprises a metallic material.

10

190. The implantable cardioverter-defibrillator of claim 189, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

SEARCHED  
INDEXED  
SERIALIZED  
FILED

15 191. The implantable cardioverter-defibrillator of claim 184, wherein the head comprises a polymeric material.

20 192. The implantable cardioverter-defibrillator of claim 191, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

25

193. The implantable cardioverter-defibrillator of claim 184, wherein the riser is substantially planar.

5        194. The implantable cardioverter-defibrillator of claim  
184, wherein the riser is substantially perpendicular to the  
electrode.

10      195. The implantable cardioverter-defibrillator of claim  
184, wherein the riser is substantially centered over the  
electrode.

196. The implantable cardioverter-defibrillator of claim  
184, wherein the head is substantially planar.

197. The implantable cardioverter-defibrillator of claim  
184, wherein the head is substantially perpendicular to the  
riser.

20      198. The implantable cardioverter-defibrillator of claim  
184, wherein the riser is between approximately 1 mm and  
approximately 10 mm in height.

25      199. The implantable cardioverter-defibrillator of claim  
198, wherein the riser comprises a proximal end, a distal end, a  
top and a bottom and wherein the proximal end is closer to the  
distal end at the top of the riser than at the bottom of the  
riser.

5

200. The implantable cardioverter-defibrillator of claim 184, wherein the electrode comprises a mesh of metallic material.

10 201. The implantable cardioverter-defibrillator of claim 200, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

15 202. The implantable cardioverter-defibrillator of claim 184, wherein the electrode comprises a substantially flat sheet of metallic material.

20 203. The implantable cardioverter-defibrillator of claim 202, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

25 204. The implantable cardioverter-defibrillator of claim 184, wherein the electrode is substantially planar.

5        205. The implantable cardioverter-defibrillator of claim  
184, wherein the electrode comprises at least one substantially  
planar surface.

10      206. The implantable cardioverter-defibrillator of claim  
205, wherein the at least one substantially planar surface has a  
surface area between approximately 100 square millimeters and  
approximately 2000 square millimeters.

15      207. The implantable cardioverter-defibrillator of claim  
184, wherein the lead electrode assembly further comprises a  
lead coupled between the electrode and the housing.

20      208. The implantable cardioverter-defibrillator of claim  
207, wherein the lead comprises one or more electrical  
conductors electrically coupled to the electrode.

25      209. The implantable cardioverter-defibrillator of claim  
208, wherein the lead further comprises an electrically  
insulating sheath, enclosing the one or more electrical  
conductors.

5        210. The implantable cardioverter-defibrillator of claim  
207, wherein the lead electrode assembly further comprises a  
connector coupled to the lead.

10      211. The implantable cardioverter-defibrillator of claim  
210, wherein the connector is electrically coupled to the  
electrode.

15      212. The implantable cardioverter-defibrillator of claim  
207, wherein the lead is between approximately 5 cm and  
approximately 52 cm in length.

20      213. The implantable cardioverter-defibrillator of claim  
212, wherein the lead is between approximately 5 cm and  
approximately 30 cm in length.

25      214. The implantable cardioverter-defibrillator of claim  
213, wherein the lead is between approximately 10 cm and  
approximately 20 cm in length.

210     215. The implantable cardioverter-defibrillator of claim  
212, wherein the lead length is one of a plurality of pre-set  
lengths.

5        216. The implantable cardioverter-defibrillator of claim  
215, wherein the pre-set lengths vary by approximately 10 cm.

217. The implantable cardioverter-defibrillator of claim  
207, wherein the lead has a proximal end and a distal end and  
10      wherein the proximal end of the lead is coupled to the  
electrode.

218. The implantable cardioverter-defibrillator of claim  
217, wherein the lead electrode assembly further comprises a  
lead fastener coupled between the proximal end of the lead and  
the electrode.

219. The implantable cardioverter-defibrillator of claim  
218, wherein the riser is coupled to the electrode along an  
20      interface line intersecting the lead fastener.

220. The implantable cardioverter-defibrillator of claim  
218, wherein the riser is coupled to the electrode along an  
interface line and wherein the lead is coupled to the lead  
25      fastener along a line of the lead that is substantially parallel  
to the interface line.

5        221. The implantable cardioverter-defibrillator of claim  
220, wherein the interface line and the line of the lead are the  
same line.

10      222. The implantable cardioverter-defibrillator of claim  
184, wherein the length of the riser is between approximately 2  
mm and approximately 6 cm.

15      223. The implantable cardioverter-defibrillator of claim  
184, wherein the length of the riser is less than the length of  
the electrode.

20      224. The implantable cardioverter-defibrillator of claim  
223, wherein the riser is coupled to the electrode along an  
interface line and the length of the riser and the length of the  
electrode are measured along the interface line.

25      225. The implantable cardioverter-defibrillator of claim  
224, wherein the electrode has a proximal end and a distal end  
and wherein the riser is closer to the proximal end of the  
electrode than the distal end of the electrode.

226. The implantable cardioverter-defibrillator of claim  
225, wherein the lead electrode assembly further comprises a

5 lead, wherein the lead is coupled to the electrode closer to the distal end of the electrode than the proximal end of the electrode.

227. The implantable cardioverter-defibrillator of claim  
10 226, wherein the lead electrode assembly further comprises a lead fastener coupled between the lead and the electrode.

228. The implantable cardioverter-defibrillator of claim  
184, wherein the lead electrode assembly further comprises a foundation.

229. The implantable cardioverter-defibrillator of claim  
228, wherein a top surface of the foundation is coupled to a bottom of the riser.

230. The implantable cardioverter-defibrillator of claim  
228, wherein a bottom surface of the foundation is coupled to and faces a top surface of the electrode.

25 231. The implantable cardioverter-defibrillator of claim  
228, wherein the lead electrode assembly further comprises a backing layer coupled between the foundation and the electrode.

5        232. The implantable cardioverter-defibrillator of claim  
229, wherein the backing layer comprises a polymeric material.

233. The implantable cardioverter-defibrillator of claim  
232, wherein the polymeric material is selected from the group  
10 consisting essentially of a polyurethane, a polyamide, a  
polyetheretherketone (PEEK), a polyether block amide (PEBA), a  
polytetrafluoroethylene (PTFE), a silicone, and mixtures  
thereof.

234. The implantable cardioverter-defibrillator of claim  
228, wherein the lead electrode assembly further comprises a  
molded cover coupled to the foundation and the electrode.

235. The implantable cardioverter-defibrillator of claim  
234, wherein the molded cover at least partially covers a top  
surface of the foundation.

236. The implantable cardioverter-defibrillator of claim  
234, wherein the molded cover comprises a skirt that partially  
25 covers a bottom surface of the electrode.

237. The implantable cardioverter-defibrillator of claim  
234, wherein the molded cover comprises a polymeric material.

5

238. The implantable cardioverter-defibrillator of claim 237, wherein the polymeric material is selected from the group consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a 10 polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

239. The implantable cardioverter-defibrillator of claim 228, wherein the foundation is substantially planar.

240. The implantable cardioverter-defibrillator of claim 228, wherein the foundation is substantially parallel to the electrode.

20 241. The implantable cardioverter-defibrillator of claim 228, wherein the foundation comprises a metallic material.

242. The implantable cardioverter-defibrillator of claim 241, wherein the metallic material is selected from the group 25 consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

5        243. The implantable cardioverter-defibrillator of claim  
241, wherein the foundation comprises a polymeric material.

244. The implantable cardioverter-defibrillator of claim  
243, wherein the polymeric material is selected from the group  
10 consisting essentially of a polyurethane, a polyamide, a  
polyetheretherketone (PEEK), a polyether block amide (PEBA), a  
polytetrafluoroethylene (PTFE), a silicone, and mixtures  
thereof.

comprising:

a plurality of tines; and  
a rod, wherein the rod is connected to the plurality  
of tines.

246. The lead electrode assembly manipulation tool of claim  
245, wherein all of the plurality of tines are parallel to each  
other.

25        247. The lead electrode assembly manipulation tool of claim  
245, wherein each of the plurality of tines is separated from  
the others by a gap.

5        248. The lead electrode assembly manipulation tool of claim  
245, wherein each of the plurality of tines comprises an inner  
side, an outer side, a proximal end and a distal end, wherein  
the inner side of each of the plurality of tines is  
substantially straight.

10

249. The lead electrode assembly manipulation tool of claim  
248, wherein the outer side of each of the plurality of tines is  
substantially straight.

SEARCHED  
INDEXED  
SERIALIZED  
FILED

25        250. The lead electrode assembly manipulation tool of claim  
248, wherein the distal end of each of the plurality of tines is  
rounded.

20        251. The lead electrode assembly manipulation tool of claim  
245, wherein the lead electrode assembly manipulation tool  
further comprises a tine base, wherein the tine base is  
connected to the rod and wherein the tine base is connected to  
the plurality of tines.

25

252. The lead electrode assembly manipulation tool of claim  
251, wherein each of the plurality of tines has a proximal end  
and a distal end and wherein the proximal end of each of the  
plurality of tines is attached to the tine base.

5

253. The lead electrode assembly manipulation tool of claim 251, wherein the rod has a proximal end and a distal end and wherein the distal end of the rod is connected to the tine base.

10 254. The lead electrode assembly manipulation tool of claim 253, wherein the lead electrode assembly manipulation tool further comprises a handle connected to the proximal end of the rod.

15 255. The lead electrode assembly manipulation tool of claim 245, wherein the rod is curved.

20 256. The lead electrode assembly manipulation tool of claim 245, wherein the plurality of tines comprise a metallic material.

25 257. The lead electrode assembly of claim 256, wherein the metallic material is selected from the group consisting essentially of titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium, and mixtures thereof.

5        258. The lead electrode assembly manipulation tool of claim  
245, wherein the plurality of tines comprises a polymeric  
material.

10      259. The lead electrode assembly manipulation tool of claim  
258, wherein the polymeric material is selected from the group  
consisting essentially of a polyurethane, a polyamide, a  
polyetheretherketone (PEEK), a polyether block amide (PEBA), a  
polytetrafluoroethylene (PTFE), a silicone, and mixtures  
thereof.

15      260. The lead electrode assembly manipulation tool of claim  
245, wherein the rod comprises a metallic material.

20      261. The lead electrode assembly of claim 260, wherein the  
metallic material is selected from the group consisting  
essentially of titanium, nickel alloys, stainless steel alloys,  
platinum, platinum iridium, and mixtures thereof.

25      262. The lead electrode assembly manipulation tool of claim  
245, wherein the rod comprises a polymeric material.

263. The lead electrode assembly manipulation tool of claim  
262, wherein the polymeric material is selected from the group

5 consisting essentially of a polyurethane, a polyamide, a polyetheretherketone (PEEK), a polyether block amide (PEBA), a polytetrafluoroethylene (PTFE), a silicone, and mixtures thereof.

10 264. A method for surgically implanting a lead electrode assembly subcutaneously outside a patient's ribcage, the method comprising the steps of:

providing a lead electrode assembly having a lead, a riser and a head;

providing a lead electrode assembly manipulation tool;

creating a subcutaneous path outside the ribcage;

capturing the lead electrode assembly with the lead electrode assembly manipulation tool;

moving the lead electrode assembly through the path;

and

releasing the lead electrode assembly from the lead electrode assembly manipulation tool.

265. The method of claim 264, wherein the step of creating  
25 a subcutaneous path outside the ribcage further comprises the steps of:

providing a hemostat;

5 creating an incision in the thoracic region of the patient; and

creating the subcutaneous path by moving the hemostat between the ribcage and the skin.

10 266. The method of claim 265, wherein the step of creating the subcutaneous path by moving the hemostat between the ribcage and the skin further comprises the step of:

moving the hemostat laterally and posteriorly around the side of the patient until the subcutaneous path terminates at a termination point such that if a straight line were drawn from the incision to the termination point, the line would intersect the heart of the patient.

15 267. The method of claim 265, wherein the step of creating the subcutaneous path by moving the hemostat between the ribcage and the skin further comprises the step of:

20 moving the hemostat laterally and posteriorly around the side of the patient until the subcutaneous path terminates at a termination point within 10 cm of the spine 25 of the patient between the third and twelfth rib.

268. The method of claim 265, wherein the incision in the thoracic region of the patient is in the anterior of the thorax.

5

269. The method of claim 265, wherein the lead electrode assembly manipulation tool comprises a rod coupled to a plurality of tines.

10

270. The method of claim 269, wherein the step of capturing the lead electrode assembly with the lead electrode assembly manipulation tool further comprises the step of:

positioning the riser of the lead electrode assembly between two of the plurality of tines of the lead electrode assembly manipulation tool.

15  
20  
25  
271. The method of claim 269, wherein the step of capturing the lead electrode assembly with the lead electrode assembly manipulation tool further comprises the step of:

holding the lead of the lead electrode assembly still relative to the rod of the lead electrode assembly manipulation tool.

272. The method of claim 269, wherein the step of capturing the lead electrode assembly with the lead electrode assembly manipulation tool further comprises the step of:

5 holding the lead of the lead electrode assembly against the rod of the lead electrode assembly manipulation tool.

273. The method of claim 269, wherein the step of releasing  
10 the lead electrode assembly from the lead electrode assembly manipulation tool further comprises the step of:

allowing the lead of the lead electrode assembly to move relative to the rod of the lead electrode assembly manipulation tool.

274. A subcutaneous implantable cardioverter-defibrillator kit for use in surgically implanting a subcutaneous implantable cardioverter-defibrillator and a lead electrode assembly within a patient comprising:

20 a tray; and

a lead electrode assembly having a riser and a head stored in the tray.

275. The subcutaneous implantable cardioverter-  
defibrillator kit of claim 274, wherein the subcutaneous  
implantable cardioverter-defibrillator kit further comprises a  
lead electrode assembly manipulation tool having a plurality of

5 times, wherein the lead electrode assembly manipulation tool is stored in the tray.

276. The subcutaneous implantable cardioverter-  
defibrillator kit of claim 274, wherein the subcutaneous  
10 implantable cardioverter-defibrillator kit further comprises a  
subcutaneous implantable cardioverter-defibrillator, wherein the  
subcutaneous implantable cardioverter-defibrillator is stored in  
the tray.

277. The subcutaneous implantable cardioverter-defibrillator kit of claim 274, wherein the subcutaneous implantable cardioverter-defibrillator kit further comprises a medical adhesive, wherein the medical adhesive is stored in the tray.

278. The subcutaneous implantable cardioverter-defibrillator kit of claim 274, wherein the subcutaneous implantable cardioverter-defibrillator kit further comprises anesthetic, wherein the anesthetic is stored in the tray.

279. The subcutaneous implantable cardioverter-defibrillator kit of claim 274, wherein the subcutaneous implantable cardioverter-defibrillator kit further comprises a

5 tube of mineral oil, wherein the tube of mineral oil is stored in the tray.

186